

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1015-JLH
)	
SAREPTA THERAPEUTICS, INC.)	DEMAND FOR JURY TRIAL
)	
Defendant.)	
<hr/>		
)	
SAREPTA THERAPEUTICS, INC. and THE)	
UNIVERSITY OF WESTERN AUSTRALIA,)	
)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD.)	
and NS PHARMA, INC.,)	
)	
Plaintiff/Counter-Defendants.)	

FINAL JURY INSTRUCTIONS (PHASE II)

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1. GENERAL INSTRUCTIONS

1.1 INTRODUCTION¹

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding the second phase of this case.

I have given you instructions at the beginning of each phase and before you began deliberations for Phase One. I will not repeat those instructions now. Instead, I will only explain the contentions of the parties and the law you will apply in this phase. Please listen very carefully to everything I say.

Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer. You will have a written copy of these instructions and my instructions from Phase One with you in the jury room for your reference during deliberations. You will also have a verdict form for this phase of the case, which will list the questions that you must answer to decide this case. We will go over that later.

¹ Source: *Personal Audio, LLC v. Google LLC*, C.A. No. 17-1751 (CFC) (slight edits).

1.2 BURDENS OF PROOF^{2 3}

As I explained to you in Phase One, in any legal action, facts must be proven by a required standard of evidence known as the “burden of proof.”

The parties have the burden of proving the amount of any monetary damages by a preponderance of the evidence. That means that the parties have to prove to you, in light of all the evidence, that what they claim is more likely true than not.

² Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW) (conforming edits); *EIS, Inc. v. Intihealth Ger GmbH*, C.A. No. 19-1227, D.I. 662 (GBW) (conforming edits); *CAO Lighting Inc. v. General Electric Company*, C.A. No. 20-681, D.I. 405 (GBW); *Cirba Inc. v. VMWare, Inc.*, C.A. No. 19-742, D.I. 1767 (GBW); *Victaulic Company v. ASC Engineered Solutions, LLC*, C.A. No. 20-887, D.I. 346 (GBW); *Board of Regents, The University of Texas System v. Boston Scientific Corp.*, C.A. No. 18-392, D.I. 326 (GBW).

³ The parties agree to revise references to “the parties” where appropriate to “Nippon Shinyaku,” “Sarepta and UWA,” or “each party” following the jury verdict in Phase One.

2. THE PARTIES AND THEIR CONTENTIONS⁴

As I did at the start of the case, I will first give you a summary of each side's contentions for this phase of the case. I will then provide you with detailed instructions on what each side must prove to win on each of its contentions.

NS Patent:

1. Whether Nippon Shinyaku has proven by a preponderance of the evidence that it suffered damages as a result of the infringement and, if so, the amount of such damages.
2. In Phase One you decided that the infringement by Sarepta of the NS Patent claim was willful, but that decision should not affect any damages award you make. I will take willfulness into account later.⁵

Wilton Patent:

1. Whether Sarepta has proven by a preponderance of the evidence that it suffered damages as a result of the infringement and, if so, the amount of such damages.
2. In Phase One you decided that any infringement by Nippon Shinyaku or NS Pharma was willful, that decision should not affect any damages award you make. I will take willfulness into account later.⁶

⁴ FCBA Model Patent Jury Instructions B.1 (conforming edits).

⁵ This instruction on willfulness should be removed if the jury does not find willful infringement.

⁶ This instruction on willfulness should be removed if the jury does not find willful infringement.

3. DAMAGES

3.1 PATENT INFRINGEMENT DAMAGES - GENERALLY⁷

[Nippon Shinyaku and NS Pharma's Proposal]: I will now give you some instructions related to damages.

The party asserting infringement has the burden to prove each element of its damages, including the amount of the damages, by a preponderance of the evidence. A party asserting infringement may only recover damages for the periods of time for which it held exclusive rights to the patents at issue. If the party asserting infringement possessed only a non-exclusive license to the patents, it cannot collect damages due to infringement during that period.^{8 9} While the party asserting infringement is not required to prove its damages with mathematical precision, it must

⁷ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

⁸ *Sicom Sys., Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005) (“A nonexclusive license confers no constitutional standing on the licensee to bring suit or even to join a suit with the patentee because a nonexclusive licensee suffers no legal injury from infringement.”); *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1265 (Fed. Cir. 2010) (a non-exclusive or “bare” licensee “suffers no legal injury from infringement”); *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004) (where party did not have exclusive rights and “received only a ‘bare license,’” it “has no entitlement under the patent statutes to itself collect lost profits damages for any losses it incurred due to infringement”).

⁹ **Sarepta's Objection**: The two preceding sentences of NS's proposal are particularly inappropriate as a jury instruction. To start, these sentences regard questions of contract interpretation, which are questions of law. Moreover, NS proposed an incomplete and misleading statement of the law. A party that has “the right to exclude others from making, using, and selling an invention described in the claims of a patent is constitutionally injured by another entity that makes, uses, or sells the invention.” *Intell. Prop. Dev., Inc. v. TCI Cablevision of Calif., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001). The Federal Circuit has explained that “constitutional standing is satisfied when a party holds at least one exclusionary right.” *Univ. of S. Fla. Rsch. Found., Inc. v. Fujifilm Med. Sys. USA, Inc.*, 19 F.4th 1315, 1324 (Fed. Cir. 2021) (emphasis added). Exclusionary rights involve the ability to exclude others from practicing an invention or to “forgive activities that would normally be prohibited under the patent statutes.” *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1342 (Fed. Cir. 2007).

To the extent that there remain any questions of fact for the jury to consider regarding Sarepta's entitlement to damages at the close of evidence, Sarepta submits that the parties should provide appropriately tailored jury instruction proposals at that time.

prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

The amount of damages you award must be adequate to compensate the party asserting infringement for any infringement. Parties asserting infringement may recover any damages they suffered as a result of the infringement.¹⁰ The question you must decide is, had the infringer not infringed, what would the party asserting infringement holder have made?¹¹ Damages are not meant to punish an infringer.

[Sarepta's Proposal]:¹² I will now instruct you about the measure of damages.

¹⁰ *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654-55 (1983) (“At the same time, Congress sought to ensure that the patent owner would in fact receive full compensation for ‘any damages’ he suffered as a result of the infringement.”) (quoting legislative history); *see also Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995) (en banc) (“[T]he language of the statute is expansive rather than limiting . . . providing only a lower limit and no other limitation.”).

¹¹ *Rite-Hite*, 56 F.3d at 1545 (“The question to be asked in determining damages is ‘how much had the Patent Holder and Licensee suffered by the infringement. And that question [is] primarily: had the Infringer not infringed, what would the Patent Holder–Licensee have made?’”) (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964)).

¹² *Nippon Shinyaku and NS Pharma's Objection*: A neutral, generally accepted and legally correct jury instruction should be used. Further, *Nippon Shinyaku and NS Pharma's* instruction removes the mention of unenforceability, which is not an issue for the jury.

Sarepta's Position: Sarepta's proposal – taken from the FCBA Model Patent Jury Instructions – is generally accepted, legally correct, and even handed. Contrary to *Nippon Shinyaku's* and *NS Pharma's* objection above, Sarepta's proposal omits any mention of unenforceability.

Source: FCBA Model Patent Jury Instructions B.5(5.1) (citing 35 U.S.C. § 284; *Ericsson, Inc. v. D-Link Sys.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014) (“What is taken from the owner of a utility patent (for purposes of assessing damages under § 284) is only the patented technology, and so the value to be measured is only the value of the infringing features of an accused product.”); *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014) (“No matter what the form of the royalty, a patentee must take care to seek only those damages attributable to the infringing features.”); *Calico Brand, Inc. v. Ameritek Imps., Inc.*, 527 F. App'x. 987, 996 (Fed. Cir. 2013) (“lost profits must be tied to the intrinsic value of the patented feature”); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 869 (Fed. Cir. 2010) (“the trial court must carefully tie proof of damages to the claimed invention's footprint in the market place”); *Dow Chem. Co. v. Mee Indus., Inc.*, 341

The damages you award must be adequate to compensate the party asserting infringement for the infringement. They are not meant to punish an infringer. Your damages award should put the party asserting infringement in approximately the same financial position that it would have been in had the infringement not occurred.

While the party asserting infringement is not required to prove the amount of its damages with mathematical precision, it must prove them with reasonable certainty. You may not award damages that are speculative, damages that are only possible, or damages that are based on guesswork.

There are different types of damages that the party asserting infringement may be entitled to recover. In this case, [Nippon Shinyaku, and Sarepta and UWA] seek lost profits and/or a reasonable royalty. Lost profits consist of any actual reduction in business profits the party asserting infringement suffered as a result of the other party's infringement. A reasonable royalty is defined as the money amount the party asserting infringement and the other party would have agreed upon as a fee for use of the invention at the time just prior to when infringement began. But, regardless of the type of damages you may choose to award, you must be careful to ensure that award is no more and no less than the value of the patented invention.

I will give more detailed instructions regarding damages shortly. Note, however, that the party asserting infringement is entitled to recover no less than a reasonable royalty for each infringing act.]

F.3d 1370, 1381-82 (Fed. Cir. 2003); *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 870 (Fed. Cir. 2003); *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999); *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1108-09 (Fed. Cir. 1996); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995) (en banc); *Lam, Inc. v. Johns-Manville Corp.*, 718 F.2d 1056, 1065 (Fed. Cir. 1983)).

3.2 TYPES OF DAMAGES^{13 14}

[Nippon Shinyaku and NS Pharma’s Proposal]: There are different types of damages that are available for patent infringement. In this case, each of Nippon Shinyaku and Sarepta and UWA have described damages they are seeking for patent infringement as lost profits and/or a reasonable royalty. Lost profits damages compensate the party asserting infringement for the additional profits that it would have earned if the accused infringer had not infringed. You may hear this referred to as the “but for” test. I will discuss lost profits in more detail shortly.

I will also discuss a reasonable royalty later in more detail. Generally, a reasonable royalty is defined by the patent laws as a reasonable amount that someone wanting to use the patented invention should expect to pay to the party asserting infringement and that party should expect to receive. A reasonable royalty is the minimum amount of damages that a party asserting infringement may recover.]

[Sarepta’s Proposal]:¹⁵ N/A.]

¹³ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

¹⁴ Nippon Shinyaku and NS Pharma believe it is less confusing for the jury to keep these as separate sub-headings.

¹⁵ Sarepta’s Position: This instruction is subsumed within Sarepta’s proposed instruction 3.1.

3.3 LOST PROFITS – “BUT FOR” TEST¹⁶

I will first instruct you about lost profits damages. To recover lost profits (as opposed to reasonable royalties), the party asserting infringement must show a causal relationship between the infringement and party asserting infringement’s loss of profit. In other words, the party asserting infringement must show that, but for the infringement, there is a reasonable probability that the party asserting infringement would have earned higher profits. To show this, the party asserting infringement must prove that, if there had been no infringement, it would have made some portion of the sales that the alleged infringer made of the infringing product.

[NS’s Proposal: Each party must prove this by a preponderance of the evidence, i.e., it is more likely than not that the party asserting infringement would have made additional profits if the accused infringer had not infringed.¹⁷ Part of your job is to determine what the customer who purchased the accused products from the accused infringer would have done if the alleged infringement had not occurred.¹⁸ It is important to remember that the profits I have been referring to are the profits allegedly lost by the party asserting infringement, not the profits, if any, made by the accused infringer on the allegedly infringing sales.¹⁹]

¹⁶ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2 (similar).

¹⁷ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW).

¹⁸ *Id.*

¹⁹ *Id.*

A party establishes “but for” causation and that it is entitled to an award of its lost profits (as opposed to reasonable royalties) if you find that it has proven each of the following four factors by a preponderance of the evidence:²⁰

1. That there was demand for the patented product or method;
2. That there were no available, acceptable, noninfringing substitute products, or, if there were, the market share of the number of the sales made by the alleged infringer that the party asserting infringement would have made, despite the availability of other acceptable noninfringing substitutes;
3. That the party asserting infringement had the manufacturing and marketing capacity to make any infringing sales actually made by the alleged infringer and for which the party asserting infringement seeks an award of lost profits—in other words, that the party asserting infringement was capable of satisfying the demand;
4. The amount of profit that the party asserting infringement would have made if the alleged infringer had not infringed.

²⁰ *Id.*

3.4 LOST PROFITS – DEMAND FOR PATENTED PRODUCT²¹

Demand for the patented product can be proven by significant sales of a party asserting infringement's patented product or significant sales of an infringing product containing the patented features.

²¹ Source: FCBA Model Patent Jury Instructions 5.2 (citing *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1330 (Fed. Cir. 2009)).

3.5 LOST PROFITS - ACCEPTABLE NON-INFRINGEMENT SUBSTITUTES²²

To be an “acceptable, noninfringing substitute,” a product must have the advantages of the patented invention that were important to people who purchased an alleged infringer’s product. If purchasers of an alleged infringer’s product were motivated to buy that product because of features available only from that product and a party asserting infringement’s patented product, then some other, alternative product is not an acceptable substitute, even if it otherwise competed with a party asserting infringement’s and an alleged infringer’s products. On the other hand, if the realities of the marketplace are that competitors other than the party asserting infringement would likely have captured the sales made by the infringer, despite a difference in the products, then the party asserting infringement is not entitled to lost profits on those sales.

²² Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2.

3.6 LOST PROFITS – CAPACITY²³

A party asserting infringement is only entitled to lost profits for sales it could have actually made. In other words, a party asserting infringement must show that it had the manufacturing and marketing ability to actually make the sales it allegedly lost due to the accused infringers' infringement. To be awarded lost profits based on additional sales that it claims it would have made, the party asserting infringement must prove that it was more likely than not that it would have had the capacity to manufacture enough products to make those additional sales, as well as the marketing capability to make those additional sales.

²³ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

3.7 LOST PROFITS – AMOUNT OF PROFIT²⁴

A party asserting infringement may calculate its lost profits on lost sales by computing the lost revenue for sales it claims it would have made but for the infringement and subtracting from that figure the amount of additional costs or expenses it would have incurred in making those lost sales, such as cost of goods, sales costs, packaging costs, and shipping costs. Certain fixed costs that do not vary with increases in production or scale, such as taxes, insurance, rent, and administrative overhead, should not be subtracted from a party asserting infringement's lost revenue.

²⁴ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.2 (citing *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11 (Fed. Cir. 1984)).

3.8 LOST PROFITS – INEXORABLE FLOW

[Nippon Shinyaku and NS Pharma’s Proposal]:²⁵ This instruction should not be included]

[Sarepta’s Proposal]:²⁶

²⁵ **Nippon Shinyaku and NS Pharma’s Position:** Nippon Shinyaku and NS Pharma object to the inclusion of this instruction. As explained in Nippon Shinyaku’s opposition to Sarepta’s motion for summary judgment, (D.I. 462), a showing under the “inexorable flow” doctrine is not required because—contrary to Sarepta’s characterization in this instruction—Nippon Shinyaku is seeking to recover profits it has itself lost as the sole supplier of VILTEPSO to the United States. Even if “inexorable flow” were implicated, Sarepta’s instruction inappropriately (1) states that “Nippon Shinyaku claims the lost profits of its subsidiary NS Pharma” (which Nippon Shinyaku does not and which is at most a question of fact); and (2) provides the jury no guidance regarding what to consider as evidence of inexorable flow, such as “contractual, structural, or historical” evidence supporting the flow. *See Schwendimann v. Arkwright Advanced Coating, Inc.*, 220 F. Supp. 3d 953, 975 (D. Minn. 2016) (quoting *Kowalski v. Mommy Gina Tuna Resources*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008)).

²⁶ **Sarepta’s Position:** As explained in Sarepta’s Motion for Summary Judgment of No Lost Profits (D.I. 409 at 8-9), the Federal Circuit has never affirmed an award of lost profits based on the profits of a non-party to an infringement claim flowing inexorably to its related patent-holding entity who itself does not sell a product in the United States. *See, e.g., Fujitsu Ltd. v. Tellabs, Inc.*, 539 F. App’x 1005, 1007 (Fed. Cir. 2013) (declining appeal regarding inexorable flow lost profits on procedural grounds); *see also Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1375 (Fed. Cir. 2015), *vacated sub nom. on other grounds Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, 577 U.S. 1099 (2016) (“a patentee may not claim, as its own damages, the lost profits of a related company.”). Subsequently, some courts have held that the inexorable theory is legally wrong. *See, e.g., Mars, Inc. v. TruRx LLC*, Case No. 6:13-cv-526, 2016 WL 4061981, at *2 (E.D. Tex. Apr. 29, 2016) (“To date, no case decided by the Federal Circuit has allowed a patentee to recover the lost profits of a related company as its own under the inexorable flow theory.”); *Copperhead Indus., Inc. v. Changer & Dresser, Inc.*, Case No. 1:18-cv-01228, 2020 WL 429485, at *2 (N.D. Ala. Jan. 28, 2020). The Court did not explicitly address this legal issue when it denied Sarepta’s Motion for Summary Judgment of No Lost Profits, stating only that “it appear[s] that there is a genuine dispute of material fact as to whether NS Japan has itself suffered damages in the form of lost profits.” D.I. 548. To the extent the jury is instructed on lost profits with respect to Nippon Shinyaku’s claim, which is based on the alleged lost profits of its subsidiary NS Pharma (*see* D.I. 409 at 8-13; D.I. 490 at 5-10), this instruction should be included. It clarifies for the jury that Nippon Shinyaku has the burden to show that the lost profits it seeks to recover are its, and not those of its subsidiary NS Pharma. The instruction also clarifies that, if the jury determines that Nippon Shinyaku is seeking recovery of its subsidiary’s lost profits, Nippon Shinyaku has the further burden to prove that the lost profits of that subsidiary inexorably flow to Nippon Shinyaku.

To be entitled to lost profits, a party must show that the lost profits come from the lost sales of a product the party itself was selling.²⁷ A party may not claim, as its own damages, the lost profits of a related entity, unless it shows those profits inexorably flow to it.²⁸ Inexorable means that the profits flow automatically from the related entity to the party; in other words, the related entity's profits *are* the party's profits.²⁹ Inexorable flow cannot be proven merely by an agreement to transfer profits or by ownership and control of a subsidiary by a parent.^{30]}

Source: *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008) (“Because we conclude that MEI’s profits did not—as Mars argues—flow inexorably to Mars, we, like the *Poly-America* court, need not decide whether a parent company can recover on a lost profits theory when profits of a subsidiary actually *do* flow inexorably up to the parent.”); *Intuitive Surgical, Inc. v. Auris Health, Inc.*, 2021 WL 3662842, at *3-4 (D. Del. Aug. 18, 2021) (granting summary judgment of no lost profits for lack of proof on inexorable flow).

²⁷ Source: *Kaneka Corp. v. Designs for Health, Inc.*, No. 21-209-WCB, Doc. 141 at 25 (D. Del. Mar. 3, 2023) (quoting *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1376 (Fed. Cir. 2015), *vacated on other grounds*, *Medtronic Sofamor Danek USA, Inc. v. NuVasive, Inc.*, 577 U.S. 1099, 136 S. Ct. 893, 193 L. Ed. 2d 785 (2016); *Poly-Am., L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1311 (Fed. Cir. 2004).

²⁸ Source: *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008).

²⁹ Source: *Advanced Fiber Techs. (AFT) Tr. v. J & L Fiber Servs., Inc.*, No. 1:07-CV-1191 LEK/DEP, 2015 WL 1472015, at *25 (N.D.N.Y. Mar. 31, 2015).

³⁰ Source: *Fujitsu Ltd. v. Tellabs, Inc.*, No. 09 C 4530, 2013 WL 2285794, at *8 (N.D. Ill. May 23, 2013); *Kowalski v. Mommy Gina Tuna Res.*, 574 F. Supp. 2d 1160, 1163 (D. Haw. 2008).

3.9 DAMAGES – REASONABLE ROYALTY³¹

[Nippon Shinyaku, and Sarepta and UWA are also each] seeking damages in the amount of a reasonable royalty.

The party asserting infringement is entitled to at least a reasonable royalty to compensate it for infringement.

If you find that the party asserting infringement has not proved its claim for lost profits, or has proved its claim for lost profits for only a portion of the infringing sales, then you must award that party a reasonable royalty for all infringing sales for which it has not been awarded lost profits damages.

A royalty is a payment made to a party asserting infringement in exchange for the right to make, use, or sell the claimed invention. A reasonable royalty is the royalty payment that would have resulted from a hypothetical negotiation between the party asserting infringement and the alleged infringer just before the infringement began.

In considering this hypothetical negotiation, you should focus on what the expectations of the party asserting infringement and the alleged infringer would have been if they had entered into an agreement at that time, and if they had acted reasonably in their negotiations. In determining this, you must assume that both parties to the hypothetical negotiation believed the patent was valid and infringed and that both parties were willing to enter into an agreement. The reasonable royalty you determine must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

³¹ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341; FCBA Model Patent Jury Instructions 5.5, 5.6 (similar).

Evidence of things that happened after the infringement first began can be considered in evaluating the reasonable royalty only to the extent that the evidence aids in assessing what royalty would have resulted from a hypothetical negotiation just prior to the first infringement. In determining the reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began.

3.10 REASONABLE ROYALTY – FACTORS³²

In determining a reasonable royalty, you should consider all the facts known and available to the parties at the time the infringement began. Some of the kinds of factors that you may consider in making your determination are:

1. Any royalties received by the party asserting infringement for licensing others under their respective asserted patents, proving or tending to prove an established royalty;
2. The rates paid by the accused infringer to license other patents comparable to the asserted patents.
3. The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.
5. The commercial relationship between the licensor and the licensee, such as whether or not they are competitors in the same territory in the same line of business.
6. The effect of selling the patented product in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such collateral sales.
7. The duration of the asserted patents and the term of the license.

³² Source: FCBA Model Patent Jury Instructions B.5(5.8) (edited to list all *Georgia-Pacific* factors); *Arendi S.A.R.L. v. Google LLC*, C.A. No. 13-919, D.I. 528 (JLH) (similar); *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

8. The established profitability of the patented product; its commercial success; and its current popularity.

9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.

10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

11. The extent to which the accused infringer has made use of the invention; and any evidence that shows the value of that use.

12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.

13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, business risks, or significant features or improvements added by the accused infringer.

14. The opinion testimony of qualified experts.

15. The amount that a licensor and a licensee (such as the accused infringer) would have agreed upon (at the time the infringement began) if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article made by the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a party asserting infringement who was willing to grant a license.

16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

No one factor is dispositive, and you can and should consider the evidence that has been presented to you in this case on each of these factors.

3.11 DAMAGES – TIMING³³

[Nippon Shinyaku and NS Pharma's Proposal]:³⁴ The relevant date for the hypothetical reasonable royalty negotiation is at the time the infringement began.

Damages are not based on a hindsight evaluation of what happened, but on what the parties to the hypothetical license negotiations would have agreed upon. Nevertheless, evidence relevant to the negotiation is not necessarily limited to facts that occurred on or before the date of the hypothetical negotiation. You may also consider information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after infringement started, license agreements entered into by the parties shortly after the date of the hypothetical negotiation, profits earned by the infringer, and non-infringing alternatives.]

With respect to the NS Patent, the parties agree that the date of commencement of damages for lost profits (if any) was August 19, 2020. The parties further agree that the hypothetical negotiation would have occurred around December 2019.³⁵

With respect to the Wilton Patent, the parties agree that the date of commencement of damages for lost profits (if any) was August 19, 2020. The parties further agree that the hypothetical negotiation would have occurred in August 2020.³⁶

³³ Source: *Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125, D.I. 605 (GBW); *Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, No. 15-1168, D.I. 341.

³⁴ **Sarepta's Position**: Nippon Shinyaku's proposed instruction is duplicative of other instructions and unnecessarily omits the parties' undisputed first dates of infringement.

³⁵ *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, D.I. 767.

³⁶ *Sunoco Partners Marketing & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, D.I. 767.

[Nippon Shinyaku and NS Pharma's Proposal]³⁷³⁸ The parties dispute whether Sarepta has met its burden of proof to establish it is entitled to damages for the time period from April 1, 2021 through May 11, 2022.]

³⁷ Nippon Shinyaku's Position: This instruction is consistent with Nippon Shinyaku's proposed jury verdict form and reflects the fact that the parties dispute whether Sarepta has met its burden to prove damages for the entire alleged damages period because it has not joined ST Holdings Two (the exclusive licensee from April 1, 2021 through May 11, 2022). *See Aspex Eyewear, Inc. v. Miracle Optics, Inc.*, 434 F.3d 1336, 1344 (Fed. Cir. 2006) (Just as "a patentee must be joined in any lawsuit involving his or her patent, there must be joinder of any exclusive licensee."). Nippon Shinyaku articulated why Sarepta and UWA would not be entitled to any damages for infringement of the Wilton Patent in its letter brief, D.I. 568, at 2 n.2, and stated Nippon Shinyaku would not object to joinder of ST Holdings Two as a counter-plaintiff to the case. Sarepta and UWA failed to do so. Without the exclusive licensee joined as a counter-plaintiff, Sarepta and UWA cannot collect damages for this time period.

³⁸ Sarepta's Position: This instruction is improper and NS has not cited any case including a similar instruction. The jury instructions are not an appropriate place to identify the parties' challenges to whether each other have met their burdens of proof.

3.12 REASONABLE ROYALTY – COMPARABLE AGREEMENTS

[Nippon Shinyaku and NS Pharma’s Proposal]: This instruction should not be included.]

[Sarepta’s Proposal]:^{39 40} When determining a reasonable royalty, you may consider evidence concerning the amounts that other parties have paid for rights to the patents in question, or for comparable rights to similar technologies. A license agreement need not be perfectly comparable to a hypothetical license that would be negotiated between the parties in order for you to consider it. However, if you choose to rely upon evidence from any license agreements, you must account for any differences between those licenses and the hypothetically negotiated license between the parties in terms of the technologies and economic circumstances of the contracting parties, when you make your reasonable royalty determination.]

³⁹ Nippon Shinyaku and NS Pharma objects to inclusion of this instruction.

⁴⁰ Sarepta’s Position: This instruction – taken from the AIPLA Model Patent Jury Instructions – explains to the jury settled law regarding the need to prove comparability of licenses to determine a reasonable royalty damages award.

4. DELIBERATION AND VERDICT⁴¹

I have completed my instructions on the law. All the instructions I gave you previously about the rules for deliberations still apply, and you will have a copy of them with you.

I will remind you that, when you start deliberating, do not talk to the jury officer, to me, or to anyone but each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can.

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

I remind you that in your deliberations you are to consider the instructions I have given you as a whole, including the instructions I gave you previously. You should not single out any part of any instruction, including this one, and ignore others. They are all equally important.

Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourself based on the evidence presented.

You may now retire and continue your deliberations.

⁴¹ Source: *Personal Audio, LLC v. Google LLC*, C.A. No. 17-1751 (CFC).